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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/366,458 08/03/99 DREYER

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HM12/0423  
GRAY CARY WARE & FREIDENRICH LLP  
4365 EXECUTIVE DRIVE  
SUITE 1600  
SAN DIEGO CA 92121-2189

EXAMINER

HUNT, J

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

04/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/366,458**

Applicant(s)

**Dreyer**

Examiner

**Jennifer Hunt**

Art Unit

**1642**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-49 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Art Unit: 1642

***Election/Restriction***

1. Upon further consideration, the previous restriction requirement is withdrawn in light of the following new restriction requirement:
2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10, drawn to a method of obtaining an enriched composition, classified in class 436, subclass 501.
  - II. Claims 11-21, drawn to a method of identifying a cell type, classified in class 435, subclass 7.2.
  - III. Claim 22, drawn to a cell, classified in class 435, subclass 325.
  - IV. Claims 23-24, drawn to a method of making a cell culture, organ, or organism, classified in class 800, subclass 8.
  - V. Claims 25-26, drawn to a method of delivering an agent to a specific cell type, classified in class 436, subclass 501.
  - VI. Claims 27-33, drawn to a method of treating a cell proliferative disorder, classified in class 424, subclass 178.1.
  - VII. Claims 34-38, drawn to a method of detecting a cell proliferative disorder, classified in class 435, subclass 7.1.

Art Unit: 1642

- VIII. Claims 39-40, drawn to a method of detecting a polynucleotide variation, classified in class 536, subclass 24.33.
- IX. Claims 41-45, drawn to a method of producing a lineage specific cell type, classified in class 435, subclass 383.
- X. Claims 46-49, drawn to a method of maintaining a lineage specific cell type, classified in class 435, subclass 374.

3. The inventions are distinct, each from the other because of the following reasons:

4. Inventions of Groups I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the cell of Group III can be made by a distinct process, for example binding to an alternative cell surface marker, or by mechanical sorting techniques.

The method of Groups I-II and IV-X are completely different methods , having different starting points, different method steps, and different outcomes. The method of Group I begins with a population of cells, and sorts them, using a binding agent. The method of Group II begins with a cell and determines it's type using detection of a receptor. The method of Group IV begins with a population of sorted cells, and from those cells produces a culture, organ, or organism. The method of Group V begins with an agent, and delivers it to a cell with a specific ligand. The method of Group VI begins with an antibody coupled to a factor and administers it

Art Unit: 1642

to a cell to inhibit the cell's growth. The method of Group VII begins with an antibody coupled to a factor and uses it to detect a particular kind of cell. The method of Group VIII begins with a nucleic acid and uses it to detect nucleic acid variations. The method of Group IX begins with a population of cells and uses an agent to commit them to a specific lineage type. The method of Group X uses a lineage maintaining agent to maintain cells of a specific lineage. As set forth herein, these are completely different methods, which are patentably distinct in their materials, steps, and outcomes.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because the search for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

Art Unit: 1642

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.


Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [[anthony.caputa@uspto.gov](mailto:anthony.caputa@uspto.gov)].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

April 19, 2001

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600